

**IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: OHIO EXECUTION
PROTOCOL LITIGATION**

**This document relates to:
PLAINTIFF JEROME HENDERSON**

Case No. 2:11-cv-1016

**JUDGE GREGORY L. FROST
Magistrate Judge Michael R. Merz**

**DEATH PENALTY CASE:
No Execution Date Currently Scheduled**

**PLAINTIFF JEROME HENDERSON'S SUPPLEMENTAL INDIVIDUAL
COMPLAINT**

Plaintiff **Jerome Henderson**, by and through counsel and pursuant to Rules 15(a) and 15(d) of the Federal Rules of Civil Procedure, and pursuant to this Court's Orders July 8, 2015, (ECF No. 523), and August 13, 2015, (ECF No. 527), as subsequently modified, hereby files this Supplemental Individual Complaint pursuant to 42 U.S.C. § 1983 for injunctive and declaratory relief, attorney fees, and costs of suit against the Defendants in the above-captioned consolidated matter.

This Supplemental Individual Complaint fully incorporates by reference each and every statement, allegation, and claim set forth in the Third Amended Omnibus Complaint (ECF No. 546, PageID 14716–15089). **The totality of this Supplemental Individual Complaint and the Third Amended Omnibus Complaint comprises Plaintiff's entire Complaint.** The statements and allegations within this Supplemental Individual Complaint are only those that are particular to Plaintiff and serve, for the Court's convenience, to supplement—not supplant—the joint statements, allegations, and claims in the Third Amended Omnibus Complaint, which contains sufficient factual allegations to state a claim for the Causes of Action alleged in that

pleading even in the absence of any Supplemental Individual Complaint. Accordingly, for convenience and efficiency of the Court, any statements, allegations, and claims included in the Third Amended Omnibus Complaint are not typically repeated here. This includes, but is not limited to, the prayer for relief, the statement of the case, and the allegations in the Third Amended Omnibus Complaint establishing subject matter jurisdiction, venue, the Defendants as Parties, the claimed Causes of Action, and myriad other factual allegations.

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I. Incorporation of Allegations in the Third Amended Omnibus Complaint by Reference

1229. Plaintiff incorporates by reference each and every allegation in the Third Amended Omnibus Complaint, ECF No. 546, PageID 14716–15089 as if fully rewritten here.

II. Allegations Relevant to Plaintiff Jerome Henderson and Defendants’ Constitutional Amendment Violations.

1230. **Plaintiff Jerome Henderson** is a United States citizen and a resident of the State of Ohio.

1231. Plaintiff is currently a death-sentenced inmate in the custody of DRC Defendants.
1232. Plaintiff is under the control and supervision of the State of Ohio Department of Rehabilitation and Correction (“DRC”), who have him incarcerated at the Chillicothe Correctional Institution, 15802 State Route 104 North, Chillicothe, Ohio under Inmate # 186-271.
1233. Plaintiff does not have a scheduled execution date at this time.
1234. Upon information and belief, if Plaintiff’s capital conviction or death sentence is not overturned in another judicial proceeding or through executive clemency, then Defendants will attempt to execute him.
1235. It is the intention of Defendants, acting in concert with other state officials not named as Defendants herein, to execute Plaintiff in the death house located on the grounds of the Southern Ohio Correctional Facility (“SOCF”) in Lucasville, Ohio, which is operated and controlled by the DRC Defendants.
1236. If Defendants attempt to execute him, Plaintiff intends to make a last statement before any such attempted execution.
1237. Upon information and belief, Plaintiff’s individual physical and/or psychological/mental characteristics and conditions indicate that employing Plan 1 of DRC Defendants’ Execution Protocol to execute him will subject him to a substantial risk of serious harm, that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants ignore. These risks are substantial when compared to the known and available alternatives.
1238. Upon information and belief, Plaintiff’s individual physical and/or psychological/mental characteristics and conditions indicate that employing Plan 2 of DRC Defendants’

Execution Protocol to execute him will subject him to a substantial risk of serious harm that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants ignore. These risks are substantial when compared to the known and available alternatives.

1239. Upon information and belief, Plaintiff has physical characteristics that will increase the difficulty of achieving peripheral IV access on Plaintiff, and/or will result in unique adverse reactions to the injection of the execution drug(s) into him, therefore increasing the substantial risk of serious harm to which he will be subjected during any attempt by Defendants to execute him using their lethal-injection Execution Protocol.
1240. Defendants' execution policy, including the written Execution Protocol, fails to account for any unique physical or psychological/mental characteristics of Plaintiff that may affect the efficacy of or the risk of harm caused by Defendants' Execution Protocol.
1241. Plaintiff's individual physical characteristics increase the risk that he will experience a substantial risk of serious harms of the type alleged throughout his Complaint if subjected to execution via DRC Defendants' Execution Protocol. Upon information and belief, those physical characteristics include, but are not limited to, that Plaintiff presents with several of the risk factors under the STOP-bang test, including that he is male, over age 50, with hypertension.
1242. Moreover, Plaintiff may develop or may currently have additional physical and/or psychological characteristics increasing the substantial risk of serious harm caused by Defendants' Execution Protocol before his execution date.
1243. Upon information and belief, in addition to failing to account for the individual physical or psychological characteristics of inmates in the execution policy, including the written

Execution Protocol, DRC Defendants have failed to properly prepare or train for any of the unique challenges Plaintiff's physical or psychological characteristics may present while carrying out an execution.

1244. Because Defendants do not account for any individual physical and/or psychological characteristics Plaintiff currently possesses or may develop before his scheduled execution date, his already substantial risk of serious harm will be greatly increased.
1245. Defendants have created, maintained and implemented a lethal injection execution policy which includes the Execution Protocol and the administration of said written protocol and Defendants' informal policies, by which they intend to execute Plaintiff.
1246. Defendants' execution policy and written Execution Protocol manifests Defendants' deliberate indifference towards Plaintiff's constitutional rights. The execution policy and Execution Protocol, as written and as applied, violate Plaintiff's constitutional rights to be free from cruel and unusual punishment which rights are secured and guaranteed to him by the Eighth and Fourteenth Amendments' limitations on Defendants' powers while acting individually or under the color and authority of state law, and/or does not protect against or prevent Defendants from conducting an unconstitutional execution because of the lack of necessary procedural safeguards.
1247. Defendants' execution policy and written Execution Protocol must contain procedural safeguards critical to ensuring against Eighth Amendment violations, and those safeguards must be followed.
1248. Plan 1 and Plan 2 of the Execution Protocol and Defendants' unwritten practices violate Plaintiff's rights under the Eighth and Fourteenth Amendments.

1249. By adhering to Plan 1 or Plan 2 of the Execution Protocol, Defendants will violate the Eighth and Fourteenth Amendments to the United States Constitution and 42 U.S.C. § 1983.
1250. In accordance with the allegations related to imported execution drugs set out in Plaintiff's Complaint, the use of imported drugs in executions creates a substantial, objectively intolerable risk of serious harm, including physical and mental pain and torturous suffering, a lingering death, an undignified, spectacle execution, and being subjected to an impermissible, unwanted, non-consensual human experimentation during Plaintiff's execution.
1251. In accordance with the allegations related to compounded execution drugs set out in Plaintiff's Complaint, the use of compounded drugs in executions creates a substantial, objectively intolerable risk of serious harm, including physical and mental pain and torturous suffering, a lingering death, an undignified, spectacle execution, and being subjected to an impermissible, unwanted, non-consensual human experimentation during Plaintiff's execution.
1252. An execution procedure that causes death by suffocation while the condemned inmate is aware of what he is experiencing violates the Eighth and Fourteenth Amendments to the Constitution of the United States.
1253. An execution procedure that causes death by heart attack while the condemned inmate is aware of what he is experiencing violates the Eighth and Fourteenth Amendments to the Constitution of the United States.

1254. An execution procedure that produces a substantial risk of psychologically or mentally torturous pain, agony and suffering violates the Eighth and Fourteenth Amendments to the Constitution of the United States.
1255. An execution procedure that produces a substantial risk of a lingering death violates the Eighth and Fourteenth Amendments to the Constitution of the United States. *In re Kemmler*, 136 U.S. 436, 447 (1890); *see also Baze v. Rees*, 553 U.S. 35, 100 (2008) (Thomas, J. concurring).
1256. An execution procedure that produces a substantial risk of causing an undignified death or a spectacle of an execution violates the Eighth and Fourteenth Amendments to the Constitution of the United States.
1257. An execution procedure that creates a substantial risk of subjecting a condemned inmate to an impermissible experimental execution that is arbitrary and capricious violates the Eighth and Fourteenth Amendments to the Constitution of the United States.
1258. An execution procedure that creates a substantial risk of subjecting a condemned inmate to maladministration or arbitrary and capricious administration of the execution protocol violates the Eighth and Fourteenth Amendments to the Constitution of the United States.
1259. An execution procedure that does not include sufficient safeguards or mechanisms in the execution policy or the Execution Protocol to prevent execution of an condemned inmate who is categorically barred from execution because he is intellectually disabled or incompetent to be executed creates a substantial risk that an ineligible person will be executed, and therefore facially violates the Eighth and Fourteenth Amendments to the Constitution of the United States.

1260. Plaintiff is subject to execution because he was convicted of aggravated murder. He greatly fears that any Drug Source Defendants who participate in his execution, in addition to lacking required skill and competence, will be unable to ignore the magnitude of Plaintiff's crime and will allow such considerations to subvert the work product.
1261. These fears are magnified many times over because the DRC Defendants have omitted any significant oversight, redundancies, and other reviews and checks of the work product, the manufacturing facilities, manufacturing protocols and other key facets of the drug manufacturing or compounding process used by the Drug Source Defendants.
1262. Such fears were lessened before the recent changes in the Execution Protocol, when the execution drugs were obtained from reliable sources that supplied mass-produced FDA-approved drugs which had been made using sterile, rigorously inspected and controlled manufacturing facilities and without knowledge of or regard for the fact that some might be used in executions.
1263. But these fears are at the forefront now when the DRC Defendants are planning to obtain imported execution drugs manufactured overseas or compounded execution drugs, from unknown Drug Source Defendants on a custom order basis for the intended and express purpose of being used for a particular execution on a particular date against a particular inmate.
1264. The DRC Defendants' allowance of so much unchecked power over the execution process to reside with unknown Drug Source Defendants is unconscionable, exposes as illusory the DRC Defendants' purported procedural protections and repeated assurances of a commitment to an execution process that is humane and protective against human error, and is violative of Plaintiff's constitutional and statutory rights.

1265. The existence of the known, foreseeable and objectively intolerable risks identified in Plaintiff's Complaint further substantially increases the likelihood that Plaintiff will be exposed to severe harm during his execution, all to his extreme prejudice and in violation of his constitutional and statutory rights.
1266. In all the ways alleged in the Causes of Action asserted below, Defendants' execution policy and written Execution Protocol subject Plaintiff to violations of his constitutional rights. The Execution Protocol is unconstitutional, facially and as applied to Plaintiff.
1267. To the extent that Plaintiff argues that the Execution Protocol to be used by Defendants in his execution will result in cruel and unusual punishment, Plaintiff asserts his Fifth Amendment right against self-incrimination insofar as said constitutional right may permit him to decline to affirmatively plead an alternative method for execution that would not be cruel and unusual. *See United States v. Myers*, 123 F.3d 350, 359 (6th Cir. 1997) ("[T]he privilege against self-incrimination can be asserted in any proceeding, civil or criminal, administrative or judicial, investigatory or adjudicatory." (quoting *Maness v. Meyers*, 419 U.S. 449, 464 (1975))); *United States v. Rivera*, 201 F.3d 99, 101 (2d Cir. 1999) ("The Fifth Amendment provides a 'safeguard against judicially coerced self-disclosure,' and this safeguard extends to the sentencing phase of a criminal proceeding as well." (citation omitted) (quoting *Mitchell v. United States*, 526 U.S. 314, 322 (1999))).
1268. Furthermore, notwithstanding any allegation of an alternative execution method pleaded in this Individual Supplemental Complaint, Plaintiff is unable to constitutionally allege an alternative method of execution because he is insufficiently competent to be able to knowingly and willingly instruct DRC Defendants how to kill him, and/or he is

insufficiently competent to assist his attorney to identify an alternative method of execution because he has insufficient medical training and knowledge to be able to identify such an alternative or because his mental health impairments or cognitive deficiencies or intellectual disabilities render him unable to do so.

1269. In the event that it is held that Plaintiff does not possess a Fifth Amendment right protecting him from being forced to provide an alternative method of execution, and that Plaintiff is competent to allege an alternative method of execution or to assist his attorney to identify an alternative method of execution, he alleges in the following causes of action readily available, feasibly implemented alternative execution method(s) that substantially reduce the substantial risks of serious harm to which he will be subjected under the Execution Protocol.

FEDERAL LAW CLAIMS FOR RELIEF

Twentieth Cause of Action: Eighth Amendment Violation Based On Substantial Risk Of Serious Harm In The Form Of Severe, Needless Physical Pain And Suffering Due To The Identity Of The Drugs In The Execution Protocol.

1270. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here.
1271. Defendants' execution policy and written Execution Protocol violate the Eighth Amendment because Plaintiff will suffer a substantial risk of serious harm in the form of severe, needless physical pain and suffering that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore, due to the identity of the drugs called for in the Execution Protocol.
1272. Defendants know, or should know, or recklessly disregard that Plan 1 using pentobarbital creates a substantial risk of severe physical pain and suffering from suffocation.

1273. Defendants know, or should know, or recklessly disregard that Plan 2 using thiopental sodium creates a substantial risk of severe physical pain and suffering from suffocation.
1274. Defendants know, or should know, or recklessly disregard that Plan 1 using pentobarbital creates a substantial risk of severe physical pain and suffering from a heart attack.
1275. Defendants know, or should know, or recklessly disregard that Plan 2 using thiopental sodium creates a substantial risk of severe physical pain and suffering from a heart attack.
1276. Plaintiff's individual physical and/or psychological characteristics and conditions create a substantial risk that employing Defendants' Execution Protocol to execute him will subject him to a substantial risk of serious harm in the form of severe, needless physical pain and suffering, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore.
1277. Plaintiff's individual physical and/or psychological characteristics and conditions create a substantial risk that achieving peripheral IV access on him will present a problematic situation analogous to achieving IV access in the previous situations in which Defendants were unable to readily obtain IV access, which, in turn, creates a substantial risk that Plaintiff will suffer serious harm in the form of severe, needless physical pain and suffering as Defendants stab him with needles repeatedly, and that substantial risk is arbitrary and capricious, or the objectively intolerable risk of such harm that Defendants unjustifiably ignore.
1278. DRC Defendants typically and historically inject only a single 5-gram dose of the execution drug required under the Execution Protocol.
1279. There is a substantial risk that Plaintiff's brain will begin to regain awareness of what is happening to him just minutes after injection of thiopental sodium or pentobarbital as

currently contemplated in the Execution Protocol and as currently administered by DRC Defendants.

1280. There is a substantial risk that Plaintiff will not be fully anesthetized, and thus he will be aware at some level while he is experiencing the physical pain and suffering related to suffocating and/or suffering a heart attack following injection of execution drug(s) under DRC Defendants' Execution Protocol.

1281. Due to his individual physical and/or psychological conditions, there is a substantial risk that Plaintiff will have a paradoxical reaction to the execution drug(s), thereby increasing the already substantial risk that he will be aware of the physical pain and agony he will be suffering upon injection of the execution drug(s).

1282. The foregoing risks are substantial when compared to the known and available alternatives.

1283. Ensuring each of the following will significantly reduce the substantial risk of severe, needless physical pain and suffering created by Defendants carrying out an execution under the Execution Protocol using lethal injection of pentobarbital or thiopental sodium as the method of execution:

- DRC Defendants must use a Bispectral Index (BIS) machine and other brain monitoring technology in the execution chamber to properly assess Plaintiff's level of awareness throughout the execution and ensure he remains unaware throughout the procedure;
- DRC Defendants must administer inhaled anesthetics to Plaintiff before injecting Plaintiff with the execution drug;
- DRC Defendants must use accepted and scientifically reliable medical standards including the use of the appropriate brain monitoring technology, not just a stethoscope assessment as they current employ, to assess the point at which irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the brain has occurred, and must continue repeated injections of 5 grams of the execution drug every three minutes until that point has been achieved;

- DRC Defendants must not use pentobarbital and thiopental sodium in the course of the same execution;
- DRC Defendants must inject the lethal drugs bedside rather than from the equipment room through several yards of IV tubing filled with saline solution, as they currently do;
- DRC Defendants and Drug Source Defendants must present to Plaintiff written, sworn verification of having submitted to the federal FDA an IND application for the use of the particular execution drug in the form and dosage to be used against Plaintiff;
- DRC Defendants must fully and formally adopt Incident Command Systems principles into their Execution Protocol as a Core Element;
- DRC Defendants must strictly comply with all portions of their Execution Protocol;
- Defendants must employ other alternative procedures that remedy the deficiencies identified herein.

1284. Because DRC Defendants have a demonstrated history of making and implementing revisions to their Execution Protocol, because DRC Defendants have a demonstrated history of being willing to use technological assistance in pursuit of carrying out an execution, because DRC Defendants can easily inject additional amounts of the execution drug, and because DRC Defendants are purportedly already employing ICS principles in the execution context, implementing such alternative procedures in Defendants' efforts to administer the Execution Protocol is feasible and readily implemented.

1285. In the alternative, the recent adoption of the execution-secrecy provisions in Ohio Revised Code § 2949.221-222 renders Plaintiff unable to fully allege an alternative execution method at this time, because the new statute attempts to place beyond Plaintiff's ability to know information critical to determining what DRC Defendants consider to be "feasible" or "readily implemented."

Twenty-First Cause of Action: Eighth Amendment Violation Based On Substantial Risk Of Serious Harm In The Form Of Severe, Needless Physical Pain And Suffering Due To The Source Of The Drugs In The Execution Protocol.

1286. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here.
1287. Defendants' execution policy and written Execution Protocol violate the Eighth Amendment because Plaintiff will suffer a substantial risk of serious harm in the form of severe, needless physical pain and suffering that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore, due to the source of the drugs called for in the Execution Protocol.
1288. Defendants know, or should know, or recklessly disregard that Plan 1 or Plan 2 using improperly compounded or illegally imported execution drugs creates a substantial risk of severe physical pain and suffering.
1289. Plaintiff is subject to a substantial risk of serious harm in the form of severe, needless physical pain and suffering, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore, due to insufficient procedural protections related to and concerns about identity, purity, contamination, concentration, pH levels, sterility, adulteration, misbranding, expiration/beyond use date, improper storage or handling, manufacturer, dosage or administration method of the drugs to be administered to cause his death under the Execution Protocol.
1290. The recent amendments to Ohio statutory code, codified in Ohio Revised Code § 2949.221, create a substantial risk of harm by themselves, and increase the risk of harm that is already substantial, by attempting to keep secret a broad range of information

relevant to what Defendants will subject Plaintiff to in the course of carrying out his execution.

1291. Compounded pentobarbital and compounded thiopental sodium have a significant potential to be extremely alkaline, which causes extreme pain upon interaction with the blood in a person's circulatory system.
1292. There is a substantial, objectively intolerable risk that Drug Source Defendants will, whether intentionally or recklessly, manufacture or compound execution drug(s) to a pH level that is either too high or too low.
1293. There is therefore a substantial, objectively intolerable risk that DRC Defendants will inject compounded execution drugs of the improper pH level into Plaintiff's bloodstream, thereby causing Plaintiff to experience intense, burning physical pain.
1294. There is a substantial, objectively intolerable risk that Defendants Pharmacies # 1-100 and Pharmacists # 1-100 will, whether intentionally or recklessly, compound execution drug(s) that particulate or fall out of solution, which DRC Defendants will inject into Plaintiff, and the injection of compounded execution drugs that have particulated or fallen out of solution will cause Plaintiff to experience intense, burning physical pain.
1295. There is at least a substantial risk—and certainly an objectively intolerable risk—that the Drug Source Defendants will, whether intentionally or recklessly, include contaminant or some additional or unknown ingredient(s) in the execution drug(s) he or she manufactures or compounds which will not be visibly or otherwise detectable by analytical testing for potency or identity called for in the Execution Protocol, but which will, nevertheless, cause torturous physical pain and suffering to Plaintiff upon injection.

1296. There is at least a substantial risk, and an objectively intolerable risk, that Defendants will improperly label, package, ship, store, and/or prepare execution drugs such that there is a substantial risk that the drugs as ultimately injected will cause Plaintiff torturous physical pain and suffering because they have become adulterated or are otherwise no longer precisely the product compounded or manufactured by Drug Source Defendants or no longer precisely the product tested by DRC Defendants.
1297. There is at least a substantial risk, and an objectively intolerable risk, that Defendants will improperly package, ship, store, and/or prepare execution drugs such that the data obtained in analytical testing required approximately 30 days before execution by the Execution Protocol will be critically incorrect, and the drugs injected into Plaintiff will be sub-potent or super-potent or otherwise adulterated or not precisely the drugs required by the Execution Protocol, therefore subjecting Plaintiff to a substantial risk of severe torturous physical pain and suffering.
1298. There is a substantial risk that Plaintiff will not be fully anesthetized, and thus he will be aware at some level while he is experiencing the physical pain and suffering related to severe burning sensations following injection of improperly compounded or illegally imported execution drug(s) under DRC Defendants' Execution Protocol.
1299. Due to his individual physical and/or psychological conditions, there is a substantial risk that Plaintiff will have a paradoxical reaction to the improperly compounded or illegally imported execution drug(s), thereby increasing the already substantial risk that he will be aware of the physical pain and agony he will be suffering upon injection of the improperly compounded or illegally imported execution drug(s).

1300. The foregoing risks are substantial when compared to the known and available alternatives.

1301. Ensuring each of the following will significantly reduce the substantial risk of severe, needless physical pain and suffering created by Defendants carrying out an execution under the Execution Protocol using lethal injection of improperly compounded or illegally imported execution drugs:

- DRC Defendants must use a Bispectral Index (BIS) machine and other brain monitoring technology in the execution chamber to properly assess Plaintiff's level of awareness throughout the execution and ensure he remains unaware throughout the procedure;
- DRC Defendants must administer inhaled anesthetics to Plaintiff before injecting Plaintiff with the execution drug;
- DRC Defendants must use accepted and scientifically reliable medical standards including the use of the appropriate brain monitoring technology, not just a stethoscope assessment as they currently employ, to assess the point at which irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the brain has occurred, and must continue repeated injections of 5 grams of the execution drug every three minutes until that point has been achieved;
- DRC Defendants must not use pentobarbital and thiopental sodium in the course of the same execution;
- DRC Defendants must inject the lethal drugs bedside rather than from the equipment room through several yards of IV tubing filled with saline solution, as they currently do;
- DRC Defendants must use only pentobarbital or thiopental sodium that is chemically and biologically identical to Nembutal or Thiopental as sold in the United States;
- DRC Defendants must use only pentobarbital or thiopental sodium that is properly compounded in strict compliance with all requirements of USP <797>, or pentobarbital or thiopental sodium manufactured in strict compliance with all requirements of cGMPs;
- Defendants must provide to Plaintiff written, sworn verification of full compliance with all relevant manufacturing (cGMPs) or compounding (USP <797>) standards and requirements in the production of the execution drug to be

injected into Plaintiff (including all requirements for matters such as labeling, packing, shipping, storing and using drug products as defined under the applicable set of standards), with such verification performed by an independent third party mutually agreed-upon by Plaintiff and DRC Defendants, and such verification to include satisfactory assessment of all testing data and other data generated in the manufacturing or compounding process under the relevant standards;

- Defendants must present to Plaintiff written, sworn verification that the drug to be used to carry out Plaintiff's execution is compounded or manufactured and imported, as applicable, in full accordance with all federal and state statutes and administrative regulations;
- DRC Defendants must present to Plaintiff written, sworn verification of satisfaction of rigorous pre-execution analytical testing of the execution drug at a mutually agreed-upon analytical testing laboratory to ensure the finished drug product is in full compliance with USP <797> or cGMPs, as applicable;
- DRC Defendants and Drug Source Defendants must present to Plaintiff written, sworn verification of having submitted to the federal FDA an IND application for the use of the particular execution drug in the form and dosage to be used against Plaintiff;
- DRC Defendants must not use execution drugs obtained from a Drug Source Defendant who has been found to not be in compliance with the full scope of execution-related prophylactic measures proffered here, and DRC Defendants must present to Plaintiff in advance of execution written, sworn verification of full compliance with all prophylactic measures proffered here;
- DRC Defendants must not use execution drugs obtained from a Drug Source Defendant who has been found to not be in compliance with USP <797> standards during any state inspection in the last five years, and DRC Defendants must identify that Drug Source Defendant to Plaintiff in advance of execution so that Plaintiff can ensure the relevant Drug Source Defendant has not been so found; alternatively, DRC Defendants must present to Plaintiff in advance of execution written, sworn verification that Drug Source Defendant in question has not been found to not be in compliance with USP <797> standards during any state inspection in the last five years;
- DRC Defendants must not use execution drugs obtained from a Drug Source Defendant who has been found to not be in compliance with cGMP standards during any FDA or state inspection in the last five years, and DRC Defendants must identify that Drug Source Defendant to Plaintiff in advance of execution so that Plaintiff can ensure the relevant Drug Source Defendant has not been so found; alternatively, DRC Defendants must present to Plaintiff in advance of execution written, sworn verification that Drug Source Defendant in question has not been found to not be in compliance with cGMP standards during any FDA or state inspection in the last five years;

- DRC Defendants must fully and formally adopt Incident Command Systems principles into their Execution Protocol as a Core Element;
- DRC Defendants must strictly comply with all portions of their Execution Protocol;
- Defendants must employ other alternative procedures that remedy the deficiencies identified herein.

1302. Because DRC Defendants have a demonstrated history of making and implementing revisions to their Execution Protocol, because DRC Defendants have a demonstrated history of being willing to use technological assistance in pursuit of carrying out an execution, because DRC Defendants can easily inject additional amounts of the execution drug, because Defendants claim they follow all federal and state laws in carrying out an execution, and because DRC Defendants are purportedly already employing ICS principles in the execution context, implementing such alternative procedures in Defendants' efforts to administer the Execution Protocol is feasible and readily implemented.

1303. In the alternative, the recent adoption of the execution-secrecy provisions in Ohio Revised Code § 2949.221-222 renders Plaintiff unable to fully allege an alternative execution method at this time, because the new statute attempts to place beyond Plaintiff's ability to know information critical to determining what DRC Defendants consider to be "feasible" or "readily implemented."

Twenty-Second Cause of Action: Eighth Amendment Violation Based On Substantial Risk Of Serious Harm In The Form Of Severe Mental Or Psychological Pain, Suffering And Torturous Agony Due To The Identity Of The Drugs In The Execution Protocol.

1304. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here.

1305. Defendants' execution policy and written Execution Protocol violate the Eighth Amendment because Plaintiff will suffer a substantial risk of serious harm in the form of severe mental or psychological pain, suffering and torturous agony that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants ignore, due to the identity of the drugs in the Execution Protocol.
1306. Because awareness of painful stimuli comes back rapidly, within a matter of minutes, after injection of pentobarbital or thiopental sodium, there is a substantial risk that Plaintiff will not be anesthetized while he is experiencing the agonizing, terrifying and horrific mental pain and suffering related to suffocating and/or suffering a heart attack following injection of execution drug(s) under Defendants' Execution Protocol, and thus that Plaintiff's brain will be aware of what he is experiencing.
1307. Defendants know, or should know, or recklessly disregard that using Plan 1 or Plan 2 with pentobarbital or thiopental sodium as an execution drug creates a substantial risk of severe, terrifying, torturous, horrifying and agonizing mental torture, suffering and mental or psychological pain from anticipating and being aware of suffocating to death or suffering a painful heart attack.
1308. Plaintiff's individual physical and/or psychological characteristics and conditions create a substantial risk that employing pentobarbital or thiopental sodium under Plan 1 or Plan 2 respectively to execute him will subject him to a substantial risk of serious harm in the form of severe mental or psychological pain, suffering and torturous agony that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants ignore, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore.

1309. Plaintiff's individual physical and/or psychological characteristics and conditions create a substantial risk that achieving peripheral IV access on him will present a problematic situation analogous to achieving IV access in the previous situations in which Defendants were unable to readily obtain IV access, which, in turn, creates a substantial risk that Plaintiff will suffer serious harm in the form of severe mental or psychological pain, suffering and torturous agony as Defendants stab him with needles repeatedly, and that risk is arbitrary and capricious, or the objectively intolerable risk of such harm that Defendants unjustifiably ignore.

1310. There is a substantial risk that Plaintiff will have a paradoxical reaction to the execution drug(s), thereby increasing the already substantial risk that he will be aware of the physical pain and agony he will be suffering upon injection of the execution drug(s), in turn elevating the substantial risk that Plaintiff will experience agonizing, terrifying and horrific mental pain and suffering as a result.

1311. The foregoing risks are substantial when compared to the known and available alternatives.

1312. Ensuring each of the following will significantly reduce the substantial risk of severe mental or psychological pain, suffering and torturous agony created by Defendants carrying out an execution under the Execution Protocol using lethal injection of pentobarbital or thiopental sodium as the method of execution:

- DRC Defendants must use a Bispectral Index (BIS) machine and other brain monitoring technology in the execution chamber to properly assess Plaintiff's level of awareness throughout the execution and ensure he remains unaware throughout the procedure;
- DRC Defendants must administer inhaled anesthetics to Plaintiff before injecting Plaintiff with the execution drug;

- DRC Defendants must use accepted and scientifically reliable medical standards including the use of the appropriate brain monitoring technology, not just a stethoscope assessment as they current employ, to assess the point at which irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the brain has occurred, and must continue repeated injections of 5 grams of the execution drug every three minutes until that point has been achieved;
- DRC Defendants must not use pentobarbital and thiopental sodium in the course of the same execution;
- DRC Defendants must inject the lethal drugs bedside rather than from the equipment room through several yards of IV tubing filled with saline solution, as they currently do;
- DRC Defendants and Drug Source Defendants must present to Plaintiff written, sworn verification of having submitted to the federal FDA an IND application for the use of the particular execution drug in the form and dosage to be used against Plaintiff;
- DRC Defendants must fully and formally adopt Incident Command Systems principles into their Execution Protocol as a Core Element;
- DRC Defendants must strictly comply with all portions of their Execution Protocol;
- Defendants must employ other alternative procedures that remedy the deficiencies identified herein.

1313. Because DRC Defendants have a demonstrated history of making and implementing revisions to their Execution Protocol, because DRC Defendants have a demonstrated history of being willing to use technological assistance in pursuit of carrying out an execution, because DRC Defendants can easily inject additional amounts of the execution drug, and because DRC Defendants are purportedly already employing ICS principles in the execution context, implementing such alternative procedures in Defendants' efforts to administer the Execution Protocol is feasible and readily implemented.

1314. In the alternative, the recent adoption of the execution-secrecy provisions in Ohio Revised Code § 2949.221-222 renders Plaintiff unable to fully allege an alternative

execution method at this time, because the new statute attempts to place beyond Plaintiff's ability to know information critical to determining what DRC Defendants consider to be "feasible" or "readily implemented."

Twenty-Third Cause of Action: Eighth Amendment Violation Based On Substantial Risk Of Serious Harm In The Form Of Severe Mental Or Psychological Pain, Suffering And Torturous Agony Due To The Source Of The Drugs In The Execution Protocol.

1315. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here.
1316. Defendants' execution policy and written Execution Protocol violate the Eighth Amendment because Plaintiff will suffer a substantial risk of serious harm in the form of severe mental or psychological pain, suffering and torturous agony that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants ignore, due to the source of the drugs in the Execution Protocol.
1317. Defendants know, or should know, or recklessly disregard that using Plan 1 or Plan 2 with improperly compounded or illegally imported execution drugs creates a variety of substantial risks of serve physical pain and suffering identified herein, of which Plaintiff is aware, thereby creating a substantial risk of severe, terrifying, torturous, horrifying and agonizing mental torture, suffering and mental and psychological pain from anticipating and being aware of his impending death at Defendants' hands using such drugs.
1318. Because awareness of painful stimuli comes back rapidly, within a matter of minutes, after injection of pentobarbital or thiopental sodium, there is a substantial risk that Plaintiff will not be anesthetized while he is experiencing the agonizing, terrifying and horrific mental pain and suffering related to severe burning sensations or anaphylactic

shock caused by improperly compounded or manufactured execution drugs following injection of such drug(s) under Defendants' Execution Protocol, and thus that Plaintiff's brain will be aware of what he is experiencing.

1319. The foregoing risks are substantial when compared to the known and available alternatives.

1320. Ensuring each of the following will significantly reduce the substantial risk of severe mental or psychological pain, suffering and torturous agony created by Defendants carrying out an execution under the Execution Protocol using lethal injection of improperly compounded or illegally imported execution drugs:

- DRC Defendants must use a Bispectral Index (BIS) machine and other brain monitoring technology in the execution chamber to properly assess Plaintiff's level of awareness throughout the execution and ensure he remains unaware throughout the procedure;
- DRC Defendants must administer inhaled anesthetics to Plaintiff before injecting Plaintiff with the execution drug;
- DRC Defendants must use accepted and scientifically reliable medical standards including the use of the appropriate brain monitoring technology, not just a stethoscope assessment as they current employ, to assess the point at which irreversible cessation of circulatory and respiratory functions or irreversible cessation of all functions of the brain has occurred, and must continue repeated injections of 5 grams of the execution drug every three minutes until that point has been achieved;
- DRC Defendants must not use pentobarbital and thiopental sodium in the course of the same execution;
- DRC Defendants must inject the lethal drugs bedside rather than from the equipment room through several yards of IV tubing filled with saline solution, as they currently do;
- DRC Defendants must use only pentobarbital or thiopental sodium that is chemically and biologically identical to Nembutal or Thiopental as sold in the United States;
- DRC Defendants must use only pentobarbital or thiopental sodium that is properly compounded in strict compliance with all requirements of USP <797>,

or pentobarbital or thiopental sodium manufactured in strict compliance with all requirements of cGMPs;

- Defendants must provide to Plaintiff written, sworn verification of full compliance with all relevant manufacturing (cGMPs) or compounding (USP <797>) standards and requirements in the production of the execution drug to be injected into Plaintiff (including all requirements for matters such as labeling, packing, shipping, storing and using drug products as defined under the applicable set of standards), with such verification performed by an independent third party mutually agreed-upon by Plaintiff and DRC Defendants, and such verification to include satisfactory assessment of all testing data and other data generated in the manufacturing or compounding process under the relevant standards;
- Defendants must present to Plaintiff written, sworn verification that the drug to be used to carry out Plaintiff's execution is compounded or manufactured and imported, as applicable, in full accordance with all federal and state statutes and administrative regulations;
- DRC Defendants must present to Plaintiff written, sworn verification of satisfaction of rigorous pre-execution analytical testing of the execution drug at a mutually agreed-upon analytical testing laboratory to ensure the finished drug product is in full compliance with USP <797> or cGMPs, as applicable;
- DRC Defendants and Drug Source Defendants must present to Plaintiff written, sworn verification of having submitted to the federal FDA an IND application for the use of the particular execution drug in the form and dosage to be used against Plaintiff;
- DRC Defendants must not use execution drugs obtained from a Drug Source Defendant who has been found to not be in compliance with the full scope of execution-related prophylactic measures proffered here, and DRC Defendants must present to Plaintiff in advance of execution written, sworn verification of full compliance with all prophylactic measures proffered here;
- DRC Defendants must not use execution drugs obtained from a Drug Source Defendant who has been found to not be in compliance with USP <797> standards during any state inspection in the last five years, and DRC Defendants must identify that Drug Source Defendant to Plaintiff in advance of execution so that Plaintiff can ensure the relevant Drug Source Defendant has not been so found; alternatively, DRC Defendants must present to Plaintiff in advance of execution written, sworn verification that Drug Source Defendant in question has not been found to not be in compliance with USP <797> standards during any state inspection in the last five years;

- DRC Defendants must not use execution drugs obtained from a Drug Source Defendant who has been found to not be in compliance with cGMP standards during any FDA or state inspection in the last five years, and DRC Defendants must identify that Drug Source Defendant to Plaintiff in advance of execution so that Plaintiff can ensure the relevant Drug Source Defendant has not been so found; alternatively, DRC Defendants must present to Plaintiff in advance of execution written, sworn verification that Drug Source Defendant in question has not been found to not be in compliance with cGMP standards during any FDA or state inspection in the last five years;
- DRC Defendants must fully and formally adopt Incident Command Systems principles into their Execution Protocol as a Core Element;
- DRC Defendants must strictly comply with all portions of their Execution Protocol;
- Defendants must employ other alternative procedures that remedy the deficiencies identified herein.

1321. Because DRC Defendants have a demonstrated history of making and implementing revisions to their Execution Protocol, because DRC Defendants have a demonstrated history of being willing to use technological assistance in pursuit of carrying out an execution, because DRC Defendants can easily inject additional amounts of the execution drug, because Defendants claim they follow all federal and state laws in carrying out an execution, and because DRC Defendants are purportedly already employing ICS principles in the execution context, implementing such alternative procedures in Defendants' efforts to administer the Execution Protocol is feasible and readily implemented.

1322. In the alternative, the recent adoption of the execution-secrecy provisions in Ohio Revised Code § 2949.221-222 renders Plaintiff unable to fully allege an alternative execution method at this time, because the new statute attempts to place beyond Plaintiff's ability to know information critical to determining what DRC Defendants consider to be "feasible" or "readily implemented."

Twenty-Fourth Cause of Action: Eighth Amendment Violation Based On Substantial Risk Of Serious Harm In The Form Of A Lingering Death.

1323. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here.
1324. A lethal-injection execution carried out under Ohio law is explicitly required to cause death “quickly and painlessly.” Ohio Rev. Code § 2949.22.
1325. Defendants’ execution policy and written Execution Protocol violate the Eighth Amendment because Plaintiffs will suffer a substantial risk of serious harm in the form of a lingering death that is that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants ignore.
1326. Defendants know, or should know, or recklessly disregard that Plan 1 creates a substantial risk of harm in the form of a lingering death.
1327. Defendants know, or should know, or recklessly disregard that Plan 2 creates a substantial risk of harm in the form of a lingering death.
1328. Defendants know, or should know, or recklessly disregard that using improperly compounded or illegally imported execution drugs under Plan 1 or Plan 2 creates a substantial risk of harm in the form of a lingering death, as exemplified by recent executions by the State of Texas of several inmates that took 20 minutes or more following injection of compounded pentobarbital.
1329. Upon information and belief, that compounded pentobarbital used in recent Texas executions was not properly compounded in accordance with the regulations, statutes and standards to which an Ohio-licensed 503A compounding pharmacy or 503B outsourcing facility is subject.

1330. Plaintiff is subject to a substantial risk of serious harm in the form of a lingering death, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore, due to the identity, sterility, concentration, manufacturer, dosage or administration method of the drugs to be administered to cause his death under the Execution Protocol.
1331. A death occurring over a period of ten minutes or more after administration of drug is a lingering death.
1332. A death in which a condemned inmate remains clinically alive and statutorily alive for 26 minutes, 45 minutes or 70 minutes after injection of the lethal drugs is a lingering death.
1333. Under DRC Defendants' current practices and Execution Protocol, DRC Defendants use no more than 5 grams of pentobarbital or thiopental sodium from an unknown source, and then they wait until breathing and heart sounds are not discernable, without further administration of any additional doses of lethal drug even though one additional dose is contemplated, without using scientifically reliable methods to determine whether irreversible cessation of breathing and brain functions have occurred, and without administration of any resuscitation efforts if the condemned inmate is still alive after 10 minutes or more.
1334. Other than a change in the drugs used, the procedures identified in the previous paragraph that will be used to administer DRC Defendants' Execution Protocol are the same or substantially similar procedures DRC Defendants employed during the execution of Dennis McGuire.

1335. There is a substantial risk that DRC Defendants' use of the procedures set out in the Execution Protocol, or substantially similar procedures, to execute Plaintiff will produce a lingering death. That risk is illustrated by the lingering death inflicted by DRC Defendants as they used essentially identical procedures when executing McGuire.
1336. It is substantially likely that McGuire, by virtue of his heightened risk of obstruction, suffocated to death faster than one who does not present the same risk of obstruction.
1337. Thus it is substantially likely that if an inmate does not experience obstruction after being injected with the execution drugs, his death will be a lingering death taking even longer than what occurred with the McGuire execution.
1338. Because DRC Defendants believe that nothing noteworthy, abnormal, unexpected, inhumane, undignified, unlawful, or otherwise unconstitutional occurred during the McGuire execution, and that the process "worked well," there is a substantial risk that DRC Defendants will again administer their Execution Protocol procedures in a way that imposes a lingering death on Plaintiff.
1339. Plaintiff's individual physical and/or psychological characteristics and conditions create a substantial risk that employing Plan 1 or Plan 2 to execute him will subject him to a substantial risk of serious harm in the form of a lingering death that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore.

1340. Plaintiff's individual physical and/or psychological characteristics and conditions create a substantial risk that achieving peripheral IV access on him will present a problematic situation analogous to achieving IV access in the previous situations in which Defendants were unable to readily obtain IV access, which, in turn, creates a substantial risk that Plaintiff will suffer serious harm in the form of a lingering execution process leading to a lingering death as Defendants stab him with needles repeatedly, and that risk is arbitrary and capricious, or the objectively intolerable risk of such harm that Defendants unjustifiably ignore.
1341. The foregoing risks are substantial when compared to the known and available alternatives.
1342. Ensuring that Defendants abide by the alternative procedures identified herein will significantly reduce the substantial risk of Plaintiff suffering a lingering death created by Defendants carrying out an execution under the Execution Protocol.
1343. For all of the reasons identified herein, implementing such alternative procedures in Defendants' efforts to administer the Execution Protocol is feasible and readily implemented.
1344. In the alternative, the recent adoption of the execution-secrecy provisions in Ohio Revised Code § 2949.221-222 renders Plaintiff unable to fully allege an alternative execution method at this time, because the new statute attempts to place beyond Plaintiff's ability to know information critical to determining what DRC Defendants consider to be "feasible" or "readily implemented."

Twenty-Fifth Cause of Action: Eighth Amendment Violation Based On Substantial Risk Of Serious Harm In The Form Of Being The Subject Of An Undignified, Spectacle Execution Or Attempted Execution.

1345. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here.
1346. Defendants' execution policy and written Execution Protocol violate the Eighth Amendment because Plaintiff will suffer a substantial risk of serious harm in the form of being the subject of an undignified, spectacle execution or attempted execution that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore.
1347. Defendants know, or should know, or recklessly disregard that Plan 1 creates a substantial risk of harm in the form of an undignified or spectacle execution.
1348. Defendants know, or should know, or recklessly disregard that Plan 2 creates a substantial risk of harm in the form of an undignified or spectacle execution.
1349. Defendants know, or should know, or recklessly disregard that using improperly compounded or illegally imported execution drugs creates a substantial risk of harm in the form of an undignified or spectacle execution.
1350. Plaintiff is subject to a substantial risk of serious harm in the form of being the subject of an undignified, spectacle execution or attempted execution, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore, due to the identity, sterility, concentration, manufacturer, dosage or administration method of the drugs to be administered to cause his death under the Execution Protocol.
1351. The death suffered by Dennis McGuire was an undignified, spectacle execution.
1352. The death suffered by Clayton Lockett was an undignified, spectacle execution.

1353. The death suffered by Joseph Wood was an undignified, spectacle execution.
1354. The death suffered by Joseph Clark was an undignified, spectacle execution.
1355. The death suffered by Christopher Newton was an undignified, spectacle execution.
1356. The attempted execution to which Romell Broom was subjected was an undignified, spectacle of an attempted execution.
1357. A death occurring over a period of ten minutes or more after administration of drug is a lingering death.
1358. A death in which a condemned inmate remains clinically alive and statutorily alive for 26 minutes, 45 minutes or 70 minutes after injection of the lethal drugs is a lingering death.
1359. Despite a change in execution drugs, DRC Defendants have not substantively changed the procedures used to carry out the execution of Dennis McGuire.
1360. There is a substantial risk that DRC Defendants' use of the procedures set out in the Execution Protocol, or substantially similar procedures, to execute Plaintiff will produce a lingering death. That risk is illustrated by the lingering death inflicted by DRC Defendants as they used essentially identical procedures when executing McGuire and other inmates such as Clark and Newton, and attempting to execute Broom.
1361. It is substantially likely that McGuire, by virtue of his heightened risk of obstruction, suffocated to death faster than one who does not present the same risk of obstruction.
1362. Thus it is substantially likely that if an inmate does not experience obstruction after being injected with the execution drugs, his death will be a lingering death taking even longer than what occurred with the McGuire execution.
1363. Because DRC Defendants believe that nothing noteworthy, abnormal, unexpected, inhumane, undignified, unlawful, or otherwise unconstitutional occurred during the

McGuire execution, and that the process “worked well,” there is a substantial risk that DRC Defendants will again administer their Execution Protocol procedures in a way that imposes a lingering death on Plaintiff.

1364. Plaintiff’s individual physical and/or psychological characteristics and conditions create a substantial risk that employing Plan 1 or Plan 2 to execute him will subject him to a substantial risk of serious harm in the form of being the subject of an undignified, spectacle execution or attempted execution that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore.
1365. Plaintiff’s individual physical and/or psychological characteristics and conditions create a substantial risk that achieving peripheral IV access on him will present a problematic situation analogous to achieving IV access in the previous situations in which Defendants were unable to readily obtain IV access, which, in turn, creates a substantial risk that Plaintiff will suffer serious harm in the form of being the subject of an undignified, spectacle execution or attempted execution as Defendants stab him with needles repeatedly, and that risk is arbitrary and capricious, or the objectively intolerable risk of such harm that Defendants unjustifiably ignore.
1366. There is a substantial risk that when Plaintiff is declared dead he will be clinically and statutorily alive, therefore suffering the ultimate indignity of being denied life-saving medical care and treated as dead while still alive.
1367. Defendants know, or should know, that designating Plaintiff’s death be declared based upon a check for “breathing and heart sounds” shortly after the injection of execution drug(s) under the Execution Protocol will result in Plaintiff remaining clinically and statutorily alive after Defendants declare him dead.

1368. According to Defendants' Execution Protocol, should Defendants pronounce Plaintiff "deceased" by announcing a time of death, Plaintiff will be removed from the "execution bed" and his body will be disposed of. (DRC Policy 01-COMM-11, ECF No. 521-1, PageID 14174–77.)
1369. Treating Plaintiff as though he is dead, when he is still alive, is a form of disgrace and indignity prohibited by the Eighth Amendment. It denies his very humanity. *Wilkerson v. State of Utah*, 99 U.S. 130, 134-35 (1878); *see also Hope v. Pelzer*, 536 U.S. 730, 745 (2002) (Eighth Amendment prohibits punishment that is humiliating or "antithetical to human dignity"); *Trop v. Dulles*, 356 U.S. 86, 103–04 (1958) (Eighth Amendment prohibits the denial of citizenship as punishment because of the dehumanizing effects of the punishment).
1370. The foregoing risks are substantial when compared to the known and available alternatives.
1371. Ensuring that Defendants abide by the alternative procedures identified herein will significantly reduce the substantial risk of Plaintiff suffering an undignified execution or a spectacle execution created by Defendants carrying out an execution under the Execution Protocol.
1372. For all of the reasons identified herein, implementing such alternative procedures in Defendants' efforts to administer the Execution Protocol is feasible and readily implemented.

1373. In the alternative, the recent adoption of the execution-secrecy provisions in Ohio Revised Code § 2949.221-222 renders Plaintiff unable to fully allege an alternative execution method at this time, because the new statute attempts to place beyond Plaintiff's ability to know information critical to determining what DRC Defendants consider to be "feasible" or "readily implemented."

Twenty-Sixth Cause of Action: Eighth Amendment Violation Based on Substantial Risk of Serious Harm in the Form of Being Subjected to an Unwanted, Non-Consensual Human Experimentation of an Execution.

1374. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here.
1375. Defendants' execution policy and written Execution Protocol violate the Eighth Amendment because Plaintiff will suffer a substantial risk of serious harm in the form of being subjected to an unwanted, non-consensual human experimentation of an execution that that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore, including for all the reasons alleged in Plaintiff's other causes of action related to human experimentation executions.
1376. Defendants know, or should know, or recklessly disregard that Plan 1, using compounded or illegally imported execution drugs, creates a substantial risk of harm in the form of an impermissible human experimentation of an execution that is arbitrary and capricious.
1377. Defendants know, or should know, or recklessly disregard that Plan 2, using compounded or illegally imported execution drugs, creates a substantial risk of harm in the form of an impermissible human experimentation of an execution that is arbitrary and capricious.

1378. Plaintiff's individual physical and/or psychological characteristics and conditions create a substantial risk that employing Defendants' Execution Protocol to execute him will subject him to a substantial risk of serious harm in the form of being subjected to an unwanted, non-consensual human experimentation of an execution that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore.
1379. Defendants fail to train for an execution scenario that contemplates Plaintiff's unique characteristics.
1380. Defendants fail to even recognize Plaintiff's unique characteristics as it relates to carrying out his execution.
1381. Plaintiff's individual physical and/or psychological characteristics and conditions create a substantial risk that achieving peripheral IV access on him will present a problematic situation analogous to achieving IV access in the previous situations in which Defendants were unable to readily obtain IV access, which, in turn, creates a substantial risk that Plaintiff will suffer serious harm in the form of being subjected to an unwanted, non-consensual human experimentation during his attempted execution as DRC Defendants stab him with needles repeatedly, and that risk is arbitrary and capricious, or the objectively intolerable risk of such harm that DRC Defendants unjustifiably ignore.
1382. Because of the scarcity of legally obtainable drugs for use in lethal-injection executions, when and whether Defendants will carry out Plaintiff's execution is a random, arbitrary, and capricious event.
1383. What drugs are used to conduct Plaintiff's execution and the efficacy of those drugs will be up to chance.

1384. Every execution of a death-row inmate will therefore be an individual experiment and each inmate, including Plaintiff, will therefore be subject to a substantial, objectively intolerable risk of severe, unnecessary pain, suffering, degradation, humiliation, and/or disgrace.
1385. The foregoing risks are substantial when compared to the known and available alternatives.
1386. Ensuring that Defendants abide by the alternative procedures identified herein will significantly reduce the substantial risk of Plaintiff being subjected to an unwanted, non-consensual human experiment of an execution created by Defendants carrying out an execution under the Execution Protocol.
1387. For all of the reasons identified herein, implementing such alternative procedures in Defendants' efforts to administer the Execution Protocol is feasible and readily implemented.
1388. In the alternative, the recent adoption of the execution-secrecy provisions in Ohio Revised Code § 2949.221-222 renders Plaintiff unable to fully allege an alternative execution method at this time, because the new statute attempts to place beyond Plaintiff's ability to know information critical to determining what DRC Defendants consider to be "feasible" or "readily implemented."

Twenty-Seventh Cause of Action: Eighth Amendment Violation Based on Substantial Risk of Serious Harm in the Form of Maladministration or Arbitrary Administration of the Execution Protocol.

1389. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here.

1390. Defendants' execution policy and written Execution Protocol violate the Eighth Amendment because Plaintiff will suffer a substantial risk of serious harm in the form of maladministration or arbitrary administration of the Execution Protocol that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore.
1391. There is a substantial risk that Defendants will fail to strictly apply their execution policy and written Execution Protocol properly or in accordance with the requirements of said written protocol or informal policies.
1392. There is a substantial risk that Defendants will use pentobarbital or any other execution drug compounded by Drug Source Defendants that is non-sterile, impure, adulterated, sub-potent, hyper-potent, or in any other way not precisely the drugs required by Core Element # 2 of the Execution Protocol.
1393. A compounded drug that is contaminated or is sub-potent, or hyper-potent, or adulterated, or not the correct identity, or in any other way not the precise drug(s) required by the Execution Protocol poses a substantial risk of harm to Plaintiff when administered by Defendants.
1394. Defendants continue to use the same Medical Team members who have demonstrated an inability to consistently and reliably obtain peripheral IV access on condemned inmates in the execution context.
1395. Defendants' procedures for obtaining intravenous access under their overarching policy, including their written Execution Protocol, have proven to cause serious harm, including torturous physical and/or psychological pain and needless suffering and an undignified, spectacle and/or a lingering death over an extended period of time, and/or an objectively

intolerable risk of such harm that Defendants unjustifiably ignore, as personnel attempt to obtain and maintain intravenous access.

1396. Defendants have failed to promulgate formal practices to respond to the numerous well-publicized problems and complications associated with administering their overarching execution policy and written Execution Protocol, and any practices that may have been promulgated are not formally part of the written Execution Protocol and thus subject to the subjective interpretations given to them by any given Director of the DRC.

1397. These problems are repetitious and foreseeable, yet their prevalence in Ohio makes their subsequent occurrence highly likely, especially in light of the constant presence of the same problematic actors.

1398. Defendants' consistent failures, and pattern of failures, to properly and competently administer the written Execution Protocol renders the constitutionally critical safeguards—safeguards that are essential to alleviate constitutional concerns—contained in Defendants' execution policy and written Execution Protocol null and functionally nonexistent.

1399. Defendants' use of execution drugs of a different identity, concentration, purity, potency and other deviations from the drugs required by the Execution Protocol creates a substantial risk of harm, including severe, needless physical pain and suffering, severe mental or psychological pain, suffering and torturous agony, a lingering death, and an undignified, spectacle execution or attempted execution that is objectively intolerable, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore.

1400. Defendants' consistent failures, and pattern of failures to properly and competently administer the written Execution Protocol, including Defendants' individual deviations

and/or variations and Defendants' pattern of deviations and/or variations from the execution policy's and the written Execution Protocol's safeguards create a substantial risk that Plaintiff and any and all others on whom Defendants administer the Execution Protocol will not be sufficiently protected by those critical safeguards.

1401. DRC Defendants' previously admitted treatment of their written Execution Protocol's requirements as simple "guidelines," and their unlimited, open-ended redefinition of the terms "Director" and "Warden" in the Execution Protocol that reinforces that mindset, creates a substantial risk that Plaintiff and any and all others on whom Defendants administer their Execution Protocol will not be sufficiently protected by the Execution Protocol's critical safeguards.

1402. Defendants' consistent failures, and pattern of failures to properly and competently administer the written Execution Protocol, including Defendants' individual deviations and/or variations and Defendants' pattern of deviations and/or variations from the execution policy's and the written Execution Protocol's safeguards create, violates Plaintiff's Eighth and Fourteenth Amendment right to be free from cruel and unusual punishment because they create a substantial risk of serious harm, including physical and/or psychological pain, needless suffering, and a torturous, lingering, undignified and/or spectacle death that is objectively intolerable, and/or an objectively intolerable risk of such harm that Defendants unjustifiably ignore.

1403. Defendants' failure to abide by their execution policy and written Execution Protocol is a demonstrated reality rather than a mere possibility or attenuated speculation, as shown by the deviations and/or variations from key execution policy and/or written Execution Protocol requirements during executions regardless of the execution policy and written

protocol effective at the time, including under the current execution policy and written protocol.

1404. Deviations and/or variations from the execution policy and written Execution Protocol demonstrate that problems with any one particular execution are not an unforeseeable isolated mishap or innocent misadventure for which no one is liable. A long line of problematic executions in Ohio makes future problems executing Plaintiff foreseeable and highly likely.
1405. DRC Defendants' inconsistent application of Incident Command Systems principles over time creates a substantial risk that Plaintiff will not be sufficiently protected by application of ICS principles to prevent a violation of Plaintiff's Eighth Amendment rights.
1406. The deviations and/or variations, and the pattern of deviations and/or variations, from Defendants' execution policy and written Execution Protocol by many of the actors involved, whether intentional or reckless, the amount of discretion that exists under the overarching execution policy and within the written protocol, DRC Defendants' demonstrated belief that the written Execution Protocol is not mandatory but is instead guidelines, the substantial evidence of Defendants' incompetence or inability to perform in the execution context, and the historical inconsistency in applying ICS principles in the execution context cumulatively point to a substantial risk of serious harm and/or an objectively intolerable risk of harm, in violation of Plaintiff's Eighth and Fourteenth Amendment rights.
1407. This includes intentional and/or willful and/or reckless disregard for the Execution Protocol's requirements, as well as negligent, reckless, and/or willful failure to follow the

written protocol's requirements in administration of Defendants' overarching execution policy.

1408. Defendants, while making arbitrary and reckless deviations, nonetheless fail to take into account Plaintiff's physical health, mental health, and other individual characteristics that make him vulnerable to experiencing a substantial risk of serious pain and/or an objectively intolerable risk of harm.
1409. Defendants' overarching execution policy, including their pattern of deviations and/or variations from their written protocol and the unlimited discretion they claim, is arbitrary, capricious, cruel and unusual, unjustifiably ignores an objectively intolerable risk of harm, and will violate Plaintiff's rights under the Eighth and Fourteenth Amendments.
1410. Plaintiff's individual physical and/or psychological characteristics and conditions create a substantial risk that employing DRC Defendants' Execution Protocol to execute him will subject him to a substantial risk of serious harm in the form of maladministration or arbitrary administration of the Execution Protocol that is arbitrary and capricious, or an objectively intolerable risk of such harm that Defendants unjustifiably ignore.
1411. Plaintiff's individual physical and/or psychological characteristics and conditions create a substantial risk that achieving peripheral IV access on him will present a problematic situation analogous to achieving IV access in the previous situations in which Defendants were unable to readily obtain IV access, which, in turn, creates a substantial risk that Plaintiff will suffer serious harm in the form of maladministration or arbitrary administration of the execution protocol as Defendants stab him with needles repeatedly and deviate from strict compliance with the Execution Protocol in the high-stress context

of an execution, and that risk is arbitrary and capricious, or the objectively intolerable risk of such harm that Defendants unjustifiably ignore.

1412. Defendants' Execution Protocol presents a substantial risk of harm and/or an objectively intolerable risk of harm from maladministration that Defendants unjustifiably ignore and that will result in at least the substantial risk of infliction of serious harm, including physical and/or psychological pain, needless suffering, and a torturous, lingering, undignified, spectacle death, and/or an objectively intolerable risk of such harm that Defendants unjustifiably ignore, in violation of Plaintiff's rights under the Eighth and Fourteenth Amendments.

1413. Defendants' overarching execution policy, including the broad discretion to deviate and/or to vary from Defendants' written Execution Protocol, their lengthy pattern of deviations and/or variations from the Execution Protocol and Defendants' informal policies, is arbitrary, capricious and presents a substantial risk of serious harm, including physical and/or psychological pain, a torturous, lingering or spectacle death that does not accord with the dignity of man, and/or creates an objectively intolerable risk of harm that Defendants unjustifiably ignore, and/or fails to prevent Defendants from carrying out an unconstitutional execution.

1414. The foregoing risks are substantial when compared to the known and available alternatives.

1415. Ensuring that Defendants abide by the alternative procedures identified herein will significantly reduce the substantial risk of Plaintiff suffering any of the serious harms alleged herein caused by Defendants' maladministration of their Execution Protocol in the course of carrying out Plaintiff's execution under that Execution Protocol.

1416. For all of the reasons identified herein, implementing such alternative procedures in Defendants' efforts to administer the Execution Protocol is feasible and readily implemented.

1417. In the alternative, the recent adoption of the execution-secrecy provisions in Ohio Revised Code § 2949.221-222 renders Plaintiff unable to fully allege an alternative execution method at this time, because the new statute attempts to place beyond Plaintiff's ability to know information critical to determining what DRC Defendants consider to be "feasible" or "readily implemented."

Twenty-Eighth Cause of Action: Eighth Amendment Violation Based On Substantial Risk Of Serious Harm In The Form Of Being Subjected To An Execution Protocol That Is Facially Unconstitutional Because It Does Not Preclude The Execution Of An Inmate That Is Categorically Exempt From Execution.

1418. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here.

1419. The execution of one who is intellectually disabled or incompetent to be executed constitutes cruel and unusual punishment under the Eighth Amendment.

1420. An execution protocol that would facially allow Defendants to execute one who is categorically exempt from execution fails to fully ensure adherence to the Eighth Amendment's cruel and unusual punishments clause, and thus facially violates the Eighth Amendment.

1421. An execution subject to a facially unconstitutional execution protocol violates the Eighth Amendment and is an unconstitutional execution.

1422. Defendants' execution policy and written Execution Protocol contain no procedural safeguards or mechanisms by which Defendants ensure that a condemned inmate whose execution is imminent is not intellectually disabled or incompetent to be executed.

1423. Defendants' Execution Protocol is therefore facially unconstitutional, and any execution carried out pursuant to the Execution Protocol is an unconstitutional execution.

1424. Defendants know, or should know, or recklessly disregard that the Execution Protocol and their execution policy contain no procedures or mechanisms to ensure that no execution will be carried out that is unconstitutional because execution of a particular inmate is constitutionally prohibited because of the inmate's intellectual disability or incompetence at the time of execution.

1425. There is a substantial risk of serious harm to Plaintiff that is arbitrary and capricious, or an objectively intolerable risk of serious harm that Defendants ignore, in the form of Plaintiff being subjected to execution using a facially unconstitutional and invalid execution protocol.

1426. The foregoing risks are substantial when compared to the known and available alternatives.

1427. Ensuring that the Execution Protocol expressly includes mandatory procedural safeguards and screening mechanisms by which DRC Defendants must affirmatively confirm that an inmate subject to execution is neither intellectually disabled nor incompetent, and that DRC Defendants will seek executive clemency intervention or a stay of execution from the Supreme Court of Ohio if there is any reason to believe that a condemned inmate to whom the Execution Protocol will be applied is either intellectually disabled or

incompetent, will significantly reduce the substantial risk of Plaintiff being subjected to execution pursuant to a facially unconstitutional Execution Protocol.

1428. Because DRC Defendants are already subject to a statutory requirement to raise concerns about incompetence of a condemned inmate, implementing such alternative procedures in Defendants' efforts to administer the Execution Protocol is feasible and readily implemented.

Twenty-Ninth Cause of Action: Eighth Amendment Violation Based on Deliberate Indifference or Reckless Disregard of Substantial Risk of Harm to Plaintiff.

1429. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here.
1430. All of the risks alleged in Plaintiff's Complaint are substantial, objectively intolerable, and foreseeable, including substantial risks of suffering a severe, torturous physical pain; being subjected to agony and terror constituting severe mental or psychological suffering; suffering a lingering death; suffering an undignified, spectacle execution or attempted execution; and being subjected to unwanted, non-consensual human experimentation.
1431. DRC Defendants were on notice that the experimental execution of McGuire was likely to be a horrific, torturous, undignified spectacle of an execution, but DRC Defendants proceeded with that execution anyway.
1432. DRC Defendants are aware that their institutional policies and practices in the form of the Execution Protocol and associated policies are experimental and investigational by virtue of using unapproved new drugs and by using drugs for which no Investigational New Drug application has been submitted.

1433. Drug Source Defendants are aware that their institutional policies and practices as it relates to producing execution drugs to DRC Defendants violate federal and state laws as articulated throughout this Complaint.
1434. Drug Source Defendants' exhibit gross or systematic deficiencies in staffing, facilities, equipment and procedures for compounding, manufacturing, importing, shipping, storing, handling, packaging, labeling, dispensing, distributing, or administering execution drugs.
1435. DRC Defendants are aware that their institutional policies and practices in the form of the Execution Protocol and associated policies expose Plaintiff to significant risks of harm and to significant burdens on their fundamental rights based on the inclusion of compounded or imported execution drugs to carry out an execution, based on Drug Source Defendants' pattern of conduct in violating mandatory federal and state laws by compounding or importing execution drugs or their gross or systematic deficiencies in staffing, facilities, equipment and procedures for compounding, manufacturing, importing, shipping, storing, handling, packaging, labeling, dispensing, distributing, or administering execution drugs.
1436. Plaintiff will be subject to the psychological torture of anticipating a horrific, painful death as alleged in this Complaint.
1437. Plaintiff is aware of the horrific spectacle that occurred during Defendants' efforts to execute Dennis McGuire on January 16, 2014 that included procedures that are unchanged in the 2015 Execution Protocol.
1438. Plaintiff is aware that Defendants do not believe that any problems or anything out of the ordinary occurred with the McGuire execution.

1439. Plaintiff is aware of the horrific, agonizing execution of Clayton Lockett on April 29, 2014, in Oklahoma, and the similarly horrific execution of Joseph Wood on July 23, 2014, in Arizona, using an execution protocol and procedures that had received the input and positive assessment from some number of DRC Defendants and/or their counsel in this case.
1440. In addition to the botched McGuire execution, Plaintiff is aware that DRC Defendants have botched other previous executions, such as the executions of Joe Clark on May 2, 2006, Christopher Newton on May 24, 2007, and the attempted execution of Romell Broom on September 15, 2009.
1441. Plaintiff is aware that DRC Defendants have deviated from the mandates of 01-COM-11 in significant ways in past executions.
1442. Plaintiff is aware that any Drug Source Defendants will likely know for whom a particular batch of compounded execution drugs is being made, that any such Drug Source Defendants will likely know that a batch prepared in advance of Plaintiff's execution date is to be used to execute Plaintiff, and that any such Drug Source Defendants will likely know at least some basic facts about the crime for which Plaintiff is to be executed.
1443. Plaintiff is aware that there is a substantial risk that he will be subjected to a physically painful, torturous, horrifying death if Defendants attempt to execute him using the Execution Protocol.
1444. Plaintiff is aware that there is a substantial risk that he will be subjected to a lingering death that will take 45 minutes or more under Ohio law, if Defendants attempt to execute him using the Execution Protocol.

1445. Plaintiff is aware that there is a substantial risk that he will be subjected to an undignified spectacle of an execution if Defendants attempt to execute him using the Execution Protocol.
1446. Plaintiff is also aware that Defendants and/or their counsel, intentionally or unintentionally, made representations to Plaintiff's counsel or to the Court that ultimately proved to be untrue, such as when various DRC actors provided false sworn testimony, or when Defendants represented in more than one instance in their April 28, 2014 after-action review of the McGuire execution that they had "discussed the events and observations of the McGuire execution" with Dr. Dershwitz, when in fact no such discussions with Dr. Dershwitz took place.
1447. Plaintiff is also aware that Defendants have callously disregarded concerns about lawless activity related to execution drugs, and attempt or will attempt instead to hide such lawlessness through invocation of the secrecy provisions in Ohio Revised Code § 2949.221–222, for which Defendant Mohr aggressively lobbied and which Defendant Kasich signed into law.
1448. Plaintiff is aware of the risks alleged in this Complaint, well in advance of his execution, based on his knowledge about: Defendants' Execution Protocol; Defendants' track record in administering their Execution Protocol; Defendants' inability to legally obtain any effective drugs that will not cause severe, unnecessary pain, suffering, degradation, humiliation, and/or disgrace; Plaintiff's own individual physical and mental/psychological characteristics; Drug Source Defendants' apparent willingness to flout scores of federal and Ohio state laws to unlawfully provide unapproved, investigational and experimental execution drugs to DRC Defendants under cloak of

secrecy; and other information regarding Defendants' actions and regarding executions carried out in other states gleaned from court filings, news reports and other sources of information.

1449. Plaintiff is also aware that Defendants have been made aware of significant deficiencies in Defendants' scheme to obtain and use compounded or imported executions drugs that will not prevent a substantial risk of subversion by Drug Source Defendants, as identified throughout this Complaint including, but not limited to, ¶¶ 149–208 of the Third Amended Omnibus Complaint.
1450. Plaintiff is also aware that, over the course of the above-captioned litigation, Defendants have made representations and promises that were later discarded when abiding by those representations and promises became a hindrance to carrying out an execution.
1451. Plaintiff is aware of the horrific, botched executions, including executions in which the condemned was subjected to a lingering death or an undignified spectacle of an execution, in Ohio and other States using protocols and procedures similar to those DRC Defendants intend to use against him under the Execution Protocol.
1452. Plaintiff is also aware that one or more of Defendants, or one or more third parties, strongly desire to have his execution carried out as soon as possible, and that Defendants are willing to go to extreme lengths and extraordinary efforts to ensure that they will be able to attempt to carry out his execution as currently scheduled.
1453. Plaintiff is also aware that Defendants, even in light of all of the above-alleged information, will intentionally apply their Execution Protocol to him in an attempt to execute him.

1454. Because Plaintiff is aware of all of these matters, there is no longer just a substantial or objectively intolerable risk of severe mental or psychological pain, suffering, terror, and anguish; instead, there is the actual, current, objectively intolerable presence of severe, torturous mental or psychological pain, suffering, horrific anxiety, terror and anguish.
1455. By their actions, Defendants are deliberately indifferent to and/or recklessly disregard, in violation of the Eighth Amendment, a substantial risk of subjecting Plaintiff to an unwanted, non-consensual human experimentation, severe, needless physical pain and suffering, severe mental or psychological pain, suffering and torturous agony, a lingering death, or an undignified, spectacle execution.

Thirtieth Cause of Action: Fourteenth Amendment Due Process Violation For Failure To Comply With Federal Investigational New Drug Application Regulations With Respect To The Method And Choice Of Drug To Be Used In Plaintiff's Execution.

1456. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here, including but not limited to ¶¶ 285–297 and 298–566 of the Third Amended Omnibus Complaint.
1457. Federal and Ohio state law prohibit marketing and distributing any “new drug” in interstate commerce unless FDA has received and approved a “new drug application” (“NDA”) that demonstrates the drug is safe and effective for a specific use or uses. 21 U.S.C. § 355(a), Ohio Rev. Code § 3715.65.
1458. If the sponsor of a new drug wishes to market the drug for additional uses not previously approved by FDA—including for example different combinations or doses—the sponsor is required to submit a separate NDA to FDA.
1459. There is no approved NDA for thiopental sodium.

1460. The approved NDA for pentobarbital does not include its use for lethal-injection human executions, and does not include its use at the doses required by the Execution Protocol.
1461. Federal and Ohio state law provides an exception to the requirement of an approved NDA for clinical investigations of a new drug, including a new use of a previously approved drug. 21 U.S.C. § 355(i).
1462. Federal law provides FDA with explicit authority to promulgate regulations for the conditions and procedures for this investigational drug use, which are incorporated in 21 C.F.R. Part 312.
1463. Without such an exception, it would be illegal to move the drug in interstate commerce for purposes of a clinical investigation.
1464. FDA's regulations state that 21 C.F.R. Part 312 applies to all "clinical investigations" of new drugs. 21 C.F.R. § 312.1(a).
1465. Section 312.3(b) defines a "clinical investigation" as follows:
- Clinical investigation* means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.
- 21 C.F.R. § 312.3(b) (emphasis in original).
1466. This definition means that using a drug outside of medical practice constitutes a "clinical investigation," and that even "medical practice" is limited to "marketed drugs."
1467. Using a drug in the course of a lethal-injection execution is not "use of a marketed drug in the course of medical practice."
1468. Under § 312.3(b), therefore, use of drugs under the Execution Protocol constitutes a clinical investigation under federal law, and requires the submission of an Investigational New Drug ("IND") application.

1469. Part 312 requires that an IND application be submitted to FDA before a clinical investigation of a new drug is undertaken: “A sponsor *shall* submit an IND to FDA if the sponsor intends to conduct a clinical investigation with an investigational new drug that is subject to 312.2(a).” 21 C.F.R. § 312.20(a) (emphasis added).
1470. An “investigational new drug” is defined under the law as a “new drug” used in a “clinical investigation.” 21 C.F.R. § 312.2(a).
1471. The “sponsor” is “a person who takes responsibility for and initiates a clinical investigation.” 21 C.F.R. § 312.3(b).
1472. Under this definition, DRC Defendants and/or Drug Source Defendants are a “sponsor” of a “clinical investigation” for the drugs’ use in a lethal-injection execution, and are thus required by law to submit an IND to FDA for this investigational use.
1473. Subpart B of Part 312 specifies the IND requirements, including the requirement that a protocol be submitted to FDA as part of the IND application. 21 C.F.R. § 312.23(a)(6).
1474. DRC Defendants must include their Execution Protocol in the IND submission to FDA and ensure that the Execution Protocol complies with the applicable, detailed regulatory requirements.
1475. Drug Source Defendants must include their relevant protocols in the IND submission to FDA and ensure that their protocols comply with the applicable, detailed regulatory requirements.
1476. Defendants are not entitled to the statutory exception to the requirement of an IND application for clinical investigations of drugs that are “lawfully marketed” in the United States. *See* 21 C.F.R. § 312.2(b)(iii)–(iv).

1477. Drugs that are compounded are not considered “lawfully marketed” for purposes of the regulations related to the IND requirements:

Studies that use a drug product that is prepared from *raw materials in place of the approved, finished product marketed by the manufacturer must be conducted under an IND* (21 C.F.R. part 312). These studies cannot meet the criteria for an exemption from the IND requirements for marketed drugs (§312.2(b)) because the drug product manufactured by the investigator or research pharmacy *is not considered to be the lawfully marketed drug*.

FDA, Guidance for Clinical Investigators, Sponsors, IRBs: Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies Can Be Conducted Without an IND (Sept. 2013) at 17 (emphasis added), available at <http://www.fda.gov/downloads/Drugs/Guidances/UCM229175.pdf>.

1478. In accordance with the law, Defendants must submit an IND application and comply with the other IND requirements 30 days before putting the Execution Protocol into effect for a lethal-injection execution.
1479. The federal IND regulations preempt any Ohio state laws, including the Execution Protocol and § 2949.22(a), that are read to authorize Defendants to conduct lethal injections pursuant to protocols that have not first been submitted to FDA for review as part of an IND, because such Ohio state laws would be in direct and positive conflict with federal law. 1962 Drug Amendments, Pub. L. 87-781, 76 Stat. 780, 793, § 202.
1480. The federal regulatory safeguards employed in the IND requirements were designed to ensure the rights and welfare of human subjects of experimentation and clinical investigation.
1481. Plaintiff is the involuntary and coerced participant in Defendants’ experimentation and clinical investigations, but he is, nevertheless, still the human subject of the clinical investigation and experimentation.

1482. The IND regulations contain no exception to the mandatory IND application process for any drug on the basis that it is used in a human execution.
1483. DRC Defendants are not exempt from the IND application regulations as it relates to execution drugs.
1484. Drug Source Defendants that are acting as 503A compounders are not exempt from the IND application framework as it relates to execution drugs due to their failure to comply with all relevant and applicable statutes and regulations, including but not limited to the requirements of USP 797 and the requirements that compounded drug products produced by a 503A compounder may only be compounded pursuant to a legally valid prescription.
1485. Drug Source Defendants that are acting as 503B outsourcing facilities are not exempt from the IND application framework as it relates to compounded pentobarbital due to their failure to comply with all relevant and applicable statutes and regulations, including but not limited to the requirements of cGMPs and the prohibition on compounding any product that is a copy or essentially a copy of an approved drug.
1486. Until the moment of death, Plaintiff maintains a constitutionally protected residual life interest; all facets of the process by which Defendants seek to deprive him of that interest, therefore, must comply with the requirements of due process.
1487. Plaintiff has a due process right to be assured that Defendants have complied with the federal IND regulations with respect to the method and choice of drug to be used in his execution.
1488. Defendants know or should know that they are subject to the mandatory IND application regulations.

1489. Defendants intentionally, with deliberate indifference, and/or recklessly disregard the mandatory IND application regulations and have not submitted a satisfactory IND to the federal FDA regarding their experimental use of pentobarbital or thiopental sodium, whether manufactured or compounded.
1490. Defendants intentionally, with deliberate indifference, and/or recklessly disregard the mandatory IND application regulations and, upon information and belief, will not submit a satisfactory IND to the federal FDA regarding their experimental use of pentobarbital or thiopental sodium, whether manufactured or compounded.
1491. Defendants' failure to comply with FDA's IND regulations related to the Execution Protocol deprive Plaintiff of a life interest without due process of law in violation of the Fourteenth Amendment.

Thirty-First Cause of Action: Equal Protection Violations Related To Defendants' Failures To Comply With The IND Application Laws.

1492. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here.
1493. Plaintiff, individually and as a member of a class of persons subject to a death sentence under Ohio law, has fundamental rights, such as those identified in ¶¶ 819–823 of the Third Amended Omnibus Complaint and the fundamental due process rights identified in ¶¶ 1456–1491 above.
1494. Plaintiff is similarly situated to others that will be human subjects of experimental and clinical investigations of Investigational New Drugs.
1495. Defendants' failures to comply with mandatory federal and Ohio state laws related to the IND application requirements are deviations from Core Elements of the Execution

Protocol for the same reasons articulated in ¶¶ 656–727 of the Third Amended Omnibus Complaint.

1496. Defendants’ intentional, deliberately indifferent, and/or reckless failure to follow the mandatory federal and Ohio state law IND application requirements treats Plaintiff disparately from others similarly situated, thereby substantially burdening Plaintiff’s fundamental rights in the ways identified in ¶ 827 of the Third Amended Omnibus Complaint and by burdening his fundamental right to a life interest in being assured that Defendants have complied with the federal IND regulations with respect to the method and choice of drug to be used in his execution before they attempt to execute him.
1497. Plaintiff is also a class of one, similarly situated with those protected from harm as subjects of human experimentation and clinical investigations by the federal IND application regulations.
1498. Defendants intentionally treat Plaintiff differently than similarly situated individuals by their arbitrary and irrational failure to follow the mandatory IND application regulations, thus irrationally subjecting Plaintiff to a heightened risk that he will suffer deprivations of his fundamental rights identified above without legitimate or rational reason.

Thirty-Second Cause of Action: Eighth Amendment Violations Based On Substantial Risk Of Serious Harm In The Form Of Severe, Needless Physical Or Mental/Psychological Pain And Suffering Due To Plaintiff’s Unique, Individual Characteristics And Application Of The Execution Protocol.

1499. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here.
1500. In addition to the many ways alleged throughout Plaintiff’s Complaint in which Plaintiff’s individual characteristics increase the risk he will experience several different

types of serious harm if subjected to DRC Defendants' Execution Protocol, his individual characteristics also increase the risks, which Defendants unjustifiably ignore, that he will also suffer serious harm in the form of severe, needless physical or mental/psychological pain and suffering in the following ways, and those risks are arbitrary and capricious, or objectively intolerable, if DRC Defendants subject Plaintiff to their Execution Protocol.

1501. Because Plaintiff presents with several risk factors for the STOP-Bang test, he is at a significant risk of suffering the phenomenon known as "air hunger" upon injection of the lethal drugs under the Execution Protocol. There will be at least a period of time following administration of the drugs when Plaintiff will remain aware of what he is enduring, including as he regains awareness after the initial injection.
1502. Accordingly, Defendants' use of the Execution Protocol will create a situation in which it is sure or very likely that Plaintiff *will* suffer torturous physical and psychological pain and suffering at DRC Defendants' hands in the execution process, let alone a "substantial risk" of that.
1503. The foregoing risks are substantial when compared to the known and available alternatives.
1504. Ensuring that Defendants abide by the alternative procedures identified herein will significantly reduce the substantial risk of severe physical or mental or psychological pain, suffering and torturous agony created by Defendants carrying out an execution under the Execution Protocol.
1505. For all of the reasons identified herein, implementing such alternative procedures in Defendants' efforts to administer the Execution Protocol is feasible and readily implemented.

1506. In the alternative, the recent adoption of the execution-secrecy provisions in Ohio Revised Code § 2949.221-222 renders Plaintiff unable to fully allege an alternative execution method at this time, because the new statute attempts to place beyond Plaintiff's ability to know information critical to determining what DRC Defendants consider to be "feasible" or "readily implemented."

Thirty-Third Cause of Action: Equal Protection Violations Related To Plaintiff's Unique, Individual Characteristics And Application Of The Law, Including DRC Defendants' Execution Protocol and Ohio's Execution Statute.

1507. Plaintiff incorporates by reference each and every statement and allegation set forth throughout his Complaint as if fully rewritten here.
1508. Due to Plaintiff's unique, individual characteristics as alleged throughout Plaintiff's Complaint, Defendants will apply the Execution Protocol and Ohio Revised Code § 2949.22(a) disparately in a way that burdens his fundamental right to be free from cruel and unusual punishment.
1509. Due to Plaintiff's unique physical characteristics, DRC Defendants will not administer to Plaintiff the professional, humane, sensitive and dignified execution which DRC Defendants have a duty to provide Plaintiff under the Execution Protocol. Instead, Plaintiff's execution will be a spectacular, undignified execution.
1510. Due to Plaintiff's unique physical characteristics, DRC Defendants will not administer to Plaintiff the quick and painless execution which DRC Defendants have a duty to provide Plaintiff under § 2949.22(a). Instead, Plaintiff's execution will be a lingering, torturous and horrifying execution.

1511. DRC Defendants will deviate from Core Elements of the Execution Protocol by failing to use the drugs required by the Execution Protocol, and by failing to use “appropriately trained and qualified” persons.
1512. The Execution Protocol provides only for injection of 5 grams of the execution drug, and perhaps for one additional dose of 5 grams. Nowhere in the Execution Protocol are additional doses of execution drug permitted to be injected.
1513. But due to Plaintiff’s unique characteristics, DRC Defendants will need to inject a 5-gram dose of execution drug every three minutes for 30 minutes or more to ensure that Plaintiff is legally and statutorily dead under Ohio law and to ensure Plaintiff never regains awareness as he is executed, far surpassing the maximum allowable amount—10 grams—that may be obtained, prepared or injected for an execution under the Execution Protocol.
1514. Injecting more than 10 grams of execution drug into Plaintiff deviates from Core Element # 2 of the Execution Protocol.
1515. Core Element # 4 of the Execution Protocol requires that all functions to be performed by Execution Team Members must be performed by appropriately trained and qualified members of the Execution Team.
1516. DRC Defendants will not be appropriately trained to administer the Execution Protocol to Plaintiff in light of his unique characteristics.
1517. DRC Defendants’ disparate treatment of Plaintiff burdens the fundamental rights against cruel and unusual punishment of a class of individuals that includes Plaintiff, namely those subject to execution at DRC Defendants’ hands.

1518. Ohio must apply its laws equally to all similarly situated persons. It does not, and will not with Plaintiff.
1519. The disparate treatment of Plaintiff does not serve a compelling governmental interest, nor is it narrowly tailored to satisfy a compelling interest.
1520. Defendants' desire to execute its death-sentenced prisoners is only a "legitimate" or, at most, a "significant" state interest, not a compelling state interest.
1521. Defendants have no interest—not even a legitimate interest—in carrying out an unconstitutional execution.
1522. Thus, any deviations from the Core Elements of the Execution Protocol, even if directly related to Plaintiff's unique characteristics, cannot be said to be tailored to a compelling governmental interest. Nor can the deviations from § 2949.22(a), or the disparate impact on Plaintiff.
1523. Defendants' disparate application of the Execution Protocol and § 2949.22(a) based on Plaintiff's unique characteristics, including their failure to actually assess and train to carry out an execution on Plaintiff in light of his unique characteristics, intentionally treats Plaintiff differently from others similarly situated—namely others subject to execution in Ohio—irrationally and arbitrarily, because that disparate treatment still involves unlawful state action which is, by definition under the law, irrational and arbitrary.
1524. Defendants' irrational and arbitrary disparate treatment of him as a class of one is to Plaintiff's detriment because it will decrease the procedural protections that are so important to protect his dignity, his humanity and his fundamental rights under the Eighth Amendment and others as alleged in Plaintiff's Complaint.

PRAYER FOR RELIEF

- G. Plaintiff incorporates by reference the prayer for relief from the Third Amended Omnibus Complaint, ECF No. 546, PageID 14716–15089.
- H. In addition to relief requested above, Plaintiff requests that this Court grant him injunctive relief under federal law in the form of the following:
 - a. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means that constitute deliberate indifference or reckless disregard of the substantial risk of harm to Plaintiff;
 - b. preliminary and permanent prohibitive injunctions preventing Defendants from executing him by means that deny his constitutional rights, as alleged herein;
- I. In addition to relief requested above, Plaintiff requests that this Court grant him declaratory relief under federal law in the form of the following:
 - a. An Order declaring that Defendants' Execution Protocol facially violates Plaintiff's constitutional rights, as alleged herein;
 - b. An Order declaring that Defendants' Execution Protocol, as applied to Plaintiff, violates Plaintiff's constitutional rights, as alleged herein.

Respectfully submitted,

Deborah L. Williams
Federal Public Defender

by

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CERTIFICATE OF SERVICE

I hereby certify that on October 9, 2015, I electronically filed the foregoing **PLAINTIFF JEROME HENDERSON'S SUPPLEMENTAL INDIVIDUAL COMPLAINT** with the Clerk of the United States District Court for the Southern District of Ohio using the CM/ECF system, which will send notification of such filing to the following at the e-mail address on file with the Court:

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